

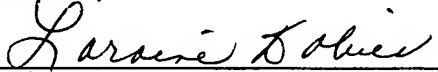
**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**



Appl. No. : 10/522,401  
Applicant(s): Taishi YOSHIDA et al.  
Filed : January 19, 2005  
For : PREVENTIVE AGENTS FOR  
DIABETES MELLITUS  
TC/A.U. : 1646  
Examiner :  
Docket No. : 04818CIP/HG  
Confirm. No.: 6305  
Customer No.: 01933

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Date of Deposit: May 3, 2005

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Laraine Dobies

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

**SUPPLEMENT TO INFORMATION DISCLOSURE STATEMENT  
FILED JANUARY 19, 2005 AND TRANSMITTAL OF ENGLISH  
TRANSLATION OF PRELIMINARY EXAMINATION REPORT**

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
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S I R :

The enclosed Forms PTO/SB/08A and PTO/SB/08B identify all of the references cited in the International Search Report of WO 2004/009118A1 which is the 18-month publication of Japanese Patent Application No. PCT/JP2003/009348 filed July 23, 2003, of which the present application is a Continuation-in-Part Application. Because priority is claimed under 35 USC 120, copies are not required. However, for the convenience of the Examiner copies are enclosed.

In addition, annexed hereto are copies of publications listed and in the above-identified application.

In the following list numbers 1 to 8 are identified in the International Search Report; also numbers 1 to 5 are cited in the specification as well. Numbers 9 and 10 are cited on page 2 of the specification; numbers 11-13 are cited on page 11 of the specification and number 14 is cited on page 16 of the specification:

1. WO 01/47935
2. J Med Chem. 2002 Aug 29;45(18):3865-77
3. Bioorg Med Chem Lett. 2001 Jan 8;11(1):17-21
4. WO 99/47549
5. N Engl J Med. 2002 Feb 7;346(6):393-403
6. Diabetes. 1980 Jan;29(1):41-9
7. N Engl J Med. 1994 Nov 3;331(18):1188-93
8. Diabetes Care. 1997 Feb;20(2):188-93
9. Diabetologia 1995;38:585-591
10. Diabetes Care 1999;22:920-924
11. Journal of Japan Diabetes Society 1999;42(5):385-404
12. Diabetes Care 1997;20:1183-1197
13. Diabetic Medicine 1998;15:539-553
14. Diabetes Research and Clinical Practice 1993;19: 49-58

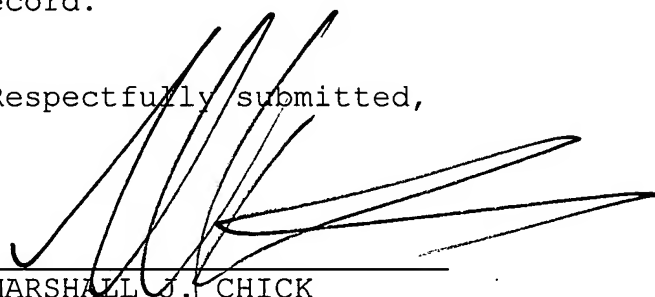
The relevance of these documents is their citation in the International Search Report and their discussion in the specification. A copy of the International Search Report is enclosed for the convenience of the Examiner.

Enclosed is an English translation of the PRELIMINARY EXAMINATION REPORT issued by WIPO (Form PCT/IPEA/409, 6 pages) and including a statement concerning several previously cited documents.

It is requested that the publications be considered with respect to the patentability of the present invention and that an initialed copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned to applicants to indicate that such publications have been considered and made "of record."

Frishauf, Holtz, Goodman  
& Chick, P.C.  
767 Third Ave., 25th Floor  
New York, NY 10017-2023  
Tel. No. (212) 319-4900  
Fax No.: (212) 319-5101  
MJC/ld

Respectfully submitted,



MARSHALL J. CHICK  
Reg. No. 26,853


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PTO/SB/08A (08-00)

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|   |   |    |   |                        |                  |
|---|---|----|---|------------------------|------------------|
| Substitute for Form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   |    |   | Application Number     | 10/522,401       |
|   |   |    |   | Filing Date            | January 19, 2005 |
|   |   |    |   | First Named Inventor   | Taishi YOSHIDA   |
|   |   |    |   | Group Art Unit         | 1646             |
|   |   |    |   | Examiner Name          |                  |
| Sheet   | 1 | of | 3 | Attorney Docket Number | 04818CIP/HG      |

## U.S. PATENT DOCUMENTS

| Exam.<br>Inits* | Cite<br>No <sup>1</sup> | Document Number | Kind<br>Code <sup>2</sup> | Name of Patentee or<br>Applicant | Publication<br>Date MM-DD-YYYY | Relevant<br>Portion |
|-----------------|-------------------------|-----------------|---------------------------|----------------------------------|--------------------------------|---------------------|
|                 |                         |                 |                           |                                  |                                |                     |

## FOREIGN PATENT DOCUMENTS

| Exam.<br>Inits* | Cite<br>No <sup>1</sup> | Offc <sup>3</sup> | Document Number <sup>4</sup> | Kind<br>Code <sup>5</sup> | Name of Patentee or<br>Applicant | Publication<br>Date MM-DD-YYYY | Relevant<br>Portion | T <sup>6</sup> |
|-----------------|-------------------------|-------------------|------------------------------|---------------------------|----------------------------------|--------------------------------|---------------------|----------------|
|                 |                         | WIPO              | WO 01/47935                  | A2                        | Metabasis Ther.                  | 07-05-2001                     |                     |                |
|                 |                         | WIPO              | WO 99/47549                  | A1                        | Ontogen Corp.                    | 09-23-1999                     |                     |                |

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

\* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Place a check here if English translation is attached.

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| Sheet   | 2                        | of  | 3 | Attorney Docket Number | 04818CIP/HG      |
| <b>OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS</b>                              |                          |   |   |                        |                  |
| Examiner<br>Initials <sup>1</sup>   | Cite<br>No. <sup>1</sup> | Include name of author (in CAPITAL LETTERS), title of article, title of item, date,<br>page(s), volume-issue number(s), publisher, city and/or country where published  |   |                        | T <sup>2</sup>   |
|   |                          | <p>WRIGHT, et al., "Anilinoquinazoline Inhibitors of Fructose-1,6-Bisphosphatase Bind at a Novel Allosteric Site: Synthesis, In Vitro Characterization, and X-ray Crystallography", <u>J. Med. Chem.</u>, 29 August, 2002 (29.08.02); 45(18): 3865-77</p> <p>WRIGHT, et al., "Allosteric inhibition of fructose-1,6-bisphosphatase by anilinoquinazo lines.", <u>Bioorg. Med. Chem. Lett.</u>, 08 January 2001 (08.01.01); 11(1):17-21</p> <p>KNOWLER, et al., "Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.", <u>N. Engl. J. Med.</u>, 07 February 2002 (07.02.02); 346(6):393-403.</p> <p>SARTOR, et al., "Ten-year follow-up of subjects with impaired glucose tolerance: prevention of diabetes by tolbutamide and diet regulation.", <u>Diabetes</u>, 1980 January; 29(1):41-9.</p> <p>NOLAN, et al., "Improvement in glucose tolerance and insulin resistance in obese subjects treated with troglitazone.", <u>N. Engl. J. Med.</u>, 03 November 1994 (03.11.94); 331(18):1188-93.</p> <p>ANTONUCCI, et al., "Impaired glucose tolerance is normalized by treatment with the thiazolidinedione troglitazone.", <u>Diabetes Care</u>, 1997 February; 20(2):188-93.</p> |   |                        |                  |
| Examiner<br>Signature   |                          |   |   | Date<br>Considered     |                  |

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS                                     |                          |  |   |                        |                    |                  |                |
| Examiner<br>Initials <sup>1</sup>   | Cite<br>No. <sup>1</sup> | Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published  |   |                        |                    |                  | T <sup>2</sup> |
|   |                          | <p>English translation of International Preliminary Examination Report Form PCT/IPEA/409 in International Application No. PCT/JP2003/009348</p> <p>YAMASAKI et al., "Asymptomatic Hyperglycaemia is associated with increased intimal plus medial thickness of the carotid artery", <u>Diabetologia</u>, 1995; 38:585-591</p> <p>TOMINAGA et al., "Impaired Glucose Tolerance Is a Risk Factor for Cardiovascular Disease, but Not Impaired Fasting Glucose", <u>Diabetes Care</u>, 1999, 22:920-924</p> <p>Journal of Japan Diabetes Society 1999; 42(5):385-404 (English Abstract is attached on pages 402-404)</p> <p>"REPORT OF THE EXPERT COMMITTEE ON THE DIAGNOSIS AND CLASSIFICATION OF DIABETES MELLITUS", <u>Diabetes Care</u>, 1997; 20:1183-1197</p> <p>ALBERTI, et al., "Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications", <u>Diabetic Medicine</u>, 1998; 15:539-553</p> <p>HOTTA et al., "The inhibitory action of buformin, a biguanide on gluconeogenesis from alanine and its transport system in rat livers", <u>Diabetes Research and Clinical Practice</u>, 1993,19:49-58</p> |   |                        |                    |                  |                |
| Examiner<br>Signature   |                          |  |   |                        | Date<br>Considered |                  |                |

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